(s) a polynucleotide sequence encoding the amino acid sequence of amino acid residues 101 to 133 of SEQ ID NO:2; and

(t) a polynucleotide sequence encoding the amino acid sequence of amino acid residues 47 to 128 of SEQ ID NO:2;

wherein said polynucleotide sequence is operatively associated with transcription and translation regulatory elements to direct transcription and translation of a polypeptide comprising said amino acid sequence.

73. (Twice amended) A method for producing a polypeptide encoded by the nucleic acid molecule of claim 44, comprising:

(a) culturing a host cell comprising the nucleic acid molecule under conditions suitable to produce the polypeptide; and

(b) recovering the polypeptide from the cell culture.

Please add new claims 154-157, as follows:

-- 154. (New) An isolated nucleic acid molecule comprising a polynucleotide sequence complementary to the polynucleotide sequence of claim 44.

155. (New) A recombinant vector comprising the isolated nucleic acid molecule of claim 154.

156. (New) A host cell comprising the vector of claim 155.

157. (New) A recombinant host cell comprising the isolated nucleic acid molecule of claim 154.--

REMARKS

Applicants recognize that the Examiner has communicated that any objection or rejection of record which is not expressly repeated in the action has been overcome by Applicant's response and withdrawn.

Applicants respectfully point out that the Examiner indicated at Page 2, Paragraph 1 of the Office Action mailed November 2, 2000 that claim 105 is under

consideration. Applicants canceled claim 105 in the Response submitted on August 17, 2000. Accordingly, Applicants submit that claim 105 is not currently pending.

Claims 29-41, 43-93, 95, 106-110, 112-125, and 127-157 are currently pending in light of the amendments above. Claims 111 and 126 have been canceled without prejudice. Claims 44 and 73 have been amended and claims 153-157 have been added to clarify certain claimed embodiments. The claims are completely supported by the specification as filed and no new matter has been introduced. Pursuant to 37 C.F.R. § 1.121(c)(1)(ii), attached hereto is an Appendix containing a marked-up version showing the changes made to claims 44 and 73 by the current amendment.

The Claim Objection Under 37 C.F.R. § 1.75(c) Has Been Obviated

Claim 73 is objected to under 37 C.F.R. § 1.75(c), as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. This rejection has been obviated by the amendments to claims 44 and 73 above. Accordingly, Applicants respectfully request that this objection be withdrawn.

Objection to Claim 44

The Examiner objects to Claim 44 as allegedly reciting an improper Markush Group. The Examiner cites M.P.E.P. 803.02 which states

> Broadly, unity of invention exists where compounds included within the Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.

The Examiner asserts that "the amino acid sequences recited in this claim do not share a substantial structural feature which is disclosed as a basis for a common utility" (Office Action, page 3). Applicants respectfully disagree with the Examiner's analysis and conclusion.

First, Applicants note that the recited members of the Markush group are polynucleotides that encoded the specified polypeptides, and not polypeptides per se. These polynucleotides all have utility, for example, as probes for isolating or analyzing the galectin 11 polynucleotides of the present invention, as asserted in the specification. Moreover, each member of the Markush group shares the common

structural feature of encoding at least a portion of SEQ ID NO:2. This structural unity is derived from their relationship to the galectin 11 polynucleotide and amino acid sequence of SEQ ID NOS:1 and 2. Thus, another unifying utility of the claimed polynucleotides, as asserted in the specification, based on this structural relationship is to use the claimed polynucleotides to produce polypeptides to raise antibodies to galectin 11. The members of the Markush group are not sufficiently unrelated so as to warrant this objection. Even if the members of the Markush group are distinct, they are unified based on their structural relationship to the overall galectin 11 nucleotide and amino acid sequence. Thus, in contrast to the Examiner's assertion, the recited polynucleotide sequences that are members of the Markush group of claim 44 share a substantial structural feature which is disclosed as a basis for common utility. Therefore, Applicants respectfully request that the objection to claim 44 as an allegedly improper Markush group be withdrawn.

Species Restriction

The Examiner contends that the instant application "contains claims directed to the patentably distinct species of amino acid sequence as listed in claim 44" *See*, Paper No. 15, Page 3, Item 6. Moreover, the Examiner has required the Applicants under 35 U.S.C. 121 "to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable." *See*, Paper No. 15, Page 3, Item 6.

Solely in order to be fully responsive, Applicants hereby provisionally elect, *with traverse*, the proposed species of claim 51 (*i.e.*, claim 44(g))

Applicants respectfully disagree with the Examiner's basis for requiring restriction of the proposed species and traverse. M.P.E.P. 803.02 states:

> If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below [followed in the instant case] and will not require restriction.

(Emphasis added).

In the instant case, the members of the Markush group are sufficiently few in number and/or closely related (see objection to claim 44, above) that a search and examination can indeed be made without serious burden. The Examiner has made absolutely no showing to the contrary. Thus, the Examiner must examine claim 44 in its entirety. Accordingly, Applicants respectfully request that the species restriction requirement be withdrawn.

In the event that the Examiner maintains the species restriction requirement, Applicants note that should no prior art be found that anticipates or makes obvious the elected species, the search of the Markush-type claim will be extended to unelected species to the extent necessary to determine the patentability of the Markush-type claim. M.P.E.P. 803.02.

Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

The Claimed Subject Matter Has Utility Under 35 U.S.C. §§ 101 And 112

Claims 29-41, 43-93, 95, and 106-153 are rejected under 35 U.S.C. § 101, first paragraph for alleged lack of utility. More particularly, the Examiner alleges at page 4 of the Office Action that the claims are "drawn to an invention with no apparent or disclosed specific and substantial credible utility."

Applicants respectfully disagree and traverse this rejection.

Applicants point to the Revised Examination Guidelines, 64 Fed. Reg. 71441 § II.B.2(b) (1999), which states (emphasis added):

> If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be *considered credible by a person of ordinary skill in the art*, do not impose a rejection based on lack of utility.

Further, § II.B.2(b)(2) clarifies (emphasis added):

> Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or

> declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide *one* credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.

The burden is on the Examiner to establish why it is more likely than not that one of ordinary skill in the art would doubt *(i.e.,* "question") the truth of the statement of utility. M.P.E.P. § 2107.01(II)(A) at 2100-[31-32]. Thus, the Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. Id. The Examiner must also present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the Applicants' assertion of utility. *See* Id.; *see also*, In re Brana, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). For the reasons set forth below, the Examiner has not met the burden that is necessary to establish and maintain a rejection for lack of utility under 35 U.S.C. § 101.

The Examiner has provided no evidence that (1) the logic underlying Applicants' assertions of utility is seriously flawed, (2) the facts upon which Applicants base the assertions of utility are inconsistent with the logic underlying the assertions, or that (3) the statements of asserted utility in the present application would be considered "false" by a person of ordinary skill in the art. The Examiner has simply stated at page 5 of the Office Action:

> The instant claims are drawn to a protein of as yet undetermined function or biological significance. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that (sic) the protein of the instant invention is associated in any way with the plurality of causally unrelated disorders that are listed on page 33 of the instant specification.

Moreover, the Examiner stated that "in the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it." *See*, Paper No. 15, Page 6, first paragraph.

Applicants contend that, in stark contrast to the Examiner's allegations, Applicants have set forth in the specification statements that clearly provide the specific, substantial, and credible asserted utility that the Examiner contends is

lacking. For example, the specification asserts at, page 1, lines 16-19; page 4, lines 10-12; page 34, line 10 to page 35, line 16; page 35, lines 28-32; page 41, line 32 to page 42, line 22; and page 45, lines 7-14 that the polypeptides of the invention are useful, for example, as a cancer diagnostic and/or therapeutic. The specification also clearly describes *in vitro* data that supports the asserted utility. For example, the specification discloses at page 63, line 10 to page 65, line 5 and Figures 5A-B that transfection of a constitutive galectin-11 expression construct into human Jurkat T-cells induces apoptosis of the transfected cells. Applicants submit that the observation that polynucleotides of the invention induce apoptosis of cells supports Applicants' assertion that the claimed polypeptides have specific, substantial, and credible uses, for example, in diagnosing and/or therapeutic treatment of a pathological conditions such as cancer. Additionally, Applicants point out that Applicants do not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty or provide actual evidence of success in treating humans where such a utility is asserted. All that is required of Applicants is that there be a *reasonable* correlation between the biological activity and the asserted utility. *See* Nelson v. Bowler, 626 F.2d 853, 857 (C.C.P.A. 1980).

Additionally, further support for the asserted utility can be found in PCT publication WO 00/63221 (Exhibit A). For example, at page 280, line 16 to page 281, line 28, *in vitro* data is discussed which demonstrates that Galectin-11 polynucleotides possess cell cycle arrest activity. Accordingly, Applicants submit that one of ordinary skill in the art would consider Applicant's asserted utility of the invention, for example, as a diagnostic and/or a therapeutic for cancer to be credible and clearly would have no basis for considering this asserted utility to be "false."

Applicants submit that, for the reasons stated above, the utility asserted in the specification for the Galectin-11 polynucleotides of the present invention is indeed *specific, substantial and credible*. Accordingly, Applicants respectfully request the rejections be reconsidered and withdrawn.

Moreover, contrary to the Examiner's contention at Page 6, Item 8 of the Office Action, Applicants have indeed adequately taught how to use the instant invention, particularly in light of the extensive teachings in the specification for using

the claimed polynucleotides. Accordingly, Applicants respectfully request that the rejections under §§ 101 and 112 for alleged lack of utility be withdrawn.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 111, 126, 136, and 145 have been rejected under 35 U.S.C. § 112, second paragraph (*See*, Paper No.15, Page 6, Item 9), as allegedly being indefinite for failing to particularly point out and claim the subject matter which the applicant regards as the invention.

In particular, the Examiner has pointed out that there is no "(e)" in the claims from which each of these claims depend. Claims 111 and 126 have been canceled rendering the rejection to claim 111 and 126 moot.

In addition, the Examiner contends that claims 136 and 145 are vague and indefinite. In particular, the Examiner contends that there is no antecedent basis for "a polypeptide encoded by."

Applicants respectfully disagree and traverse.

Applicants respectfully point out that the preamble of claims 136 and 145 recite "A method for producing a polypeptide encoded by the nucleic acid molecule of claim 121" and "A method for producing a polypeptide encoded by the nucleic acid molecule of claim 127," respectively. Accordingly, antecedent basis is required only of "the nucleic acid." A polypeptide encoded by the nucleic acid is simply an inherent property of the "the nucleic acid." The Applicant is unaware of any requirement that a newly referenced inherent property of an element in a preamble have antecedent basis. Applicants respectfully submit that claims 136 and 145 are definite and clearly point out and claim the subject matter which the applicant regards as the invention. Accordingly, Applicants respectfully request that the rejection of claims 111, 126, 136, and 145 under 35 U.S.C. § 112, second paragraph be reconsidered and withdrawn.

CONCLUSION

Applicants respectfully request that the amendments and remarks above be entered and made of record in the file history of the instant application. Applicants believe that the application is now in condition for allowance and a notice to that effect is earnestly solicited.

If there are any additional fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: MARCH 30, 2001

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